

UNITED STATES APPLICATION

FOR

GRANT OF LETTERS PATENT

**BY Domingo Rodriguez-Cue
of Williamston, North Carolina, USA**

FOR

**SYSTEM AND METHOD FOR PROVIDING WIRELESS, PAPERLESS
MEDICAL CARE AND COMMUNICATION**

**GLASGOW LAW FIRM
Intellectual Property Law
PO Box 28539
116 N. West St. Suite 270
Raleigh, NC 27611-8539**

Atty Docket No. 1268-001

1 SYSTEM AND METHOD FOR PROVIDING WIRELESS, PAPERLESS MEDICAL
2 CARE AND COMMUNICATION

3 Background of the Invention

4 (1) Field of the Invention

5 The present invention relates generally to electronic medical records and, more
6 particularly, to an integrated, electronic patient record system for providing real time
7 point of care testing, data entry, diagnosis, treatment and billing.

8 (2) Description of the Prior Art

9 A recent report by the Institute of Medicine estimated that as many as 98,000
10 people die in any given year due to hospital medical errors. That constitutes more
11 fatalities than from motor vehicle accidents, breast cancer, or AIDS. Additionally, non-
12 fatal errors can reduce the quality of life and add a financial burden to otherwise healthy
13 persons. Adding the financial cost to the human tragedy, and medical errors easily rises
14 to the top ranks of urgent, widespread public problems. The report noted that almost all
15 the available information on safety relates to hospitals, and that far too little is known
16 about other areas of care, like nursing homes, home health care, and office based care. It
17 would be expected that hazards in these areas are also common.

18 Errors are seldom caused by carelessness or lack of effort. 95% to 98% of errors
19 in medical care are "systems errors", meaning that they are characteristics of equipment,
20 procedures, job designs, or communication systems used in healthcare. Medication errors
21 alone make up a large percentage of common avoidable problems. Designing systems
22 that reduce error-prone procedures and establish proper methods can prevent errors. The
23 development of effective systems at the level of direct patient care can thus prevent the

majority of these errors. Electronic medical records (EMR) is one of these "systems"; it provides a number of tools, reminders, and system checks that can help providers reduce errors. It also allows for electronic prescription writing with remote links to pharmacies and/or hospitals and electronic orders that facilitate in-hospital patient care.

Prior art EMR systems employ various means to interface with the clinician. For example, Personal digital assistants, or PDAs, and desktop computers are commonly used. However, these methods of interfacing with the clinician are either difficult for the clinician to master and use or unsettling to the patient. In the case of PDAs, a limited amount of information is displayed to the clinician and therefore the clinician must retain in memory all information about the client or else he/she must continuously switch between data windows to refresh his/her memory. There is also no real time connection to the server allowing for true point of care medicine. In the case of desktop computers, these require the clinician to leave or turn away from the patient to input data, actions that may be unsettling to the patient, in that the patient may feel a lack of attention by the clinician. They also leave a window of opportunity for security to be breached at the client computer between uses. The desktop PC is not portable and is more costly to setup and maintain. Other systems have data inputted by the clinician but require transcribing, forward, or some other action by another person or party prior to transmission of the request. Thus, the possibility of error exists because another step performed by a person other than the clinician has been introduced into the system.

Another difficulty encountered in the integration of an EMR, laboratory, and billing systems is the integration of data from the various analytical devices used in clinical care. Manual inputting of information generated by these devices allows for

1 errors to be introduced into records; however, direct communication between the various
2 devices and the EMR is difficult to achieve because of the different connection protocols
3 used by the devices. Manual inputting of data is also time consuming, in turn taking
4 away precious patient care time. Manual input is also time-consuming in turn taking
5 away precious patient care time.

6 Finally, many systems require additional inputting of previously recorded data
7 into another format for the generation of invoices and bills. In these cases, errors such as
8 double billing or missed billing can cause financial and legal problems for insurers and
9 medical care providers alike. Thus, the prior art systems have properties that render them
10 still error-prone or difficult to use and therefore unlikely to be widely adopted.

11 Thus, there remains a need for an electronic medical record system for providing
12 real time point of care testing, data entry, billing, and treatment. The interface needs to be
13 intuitive to medical personnel and easy to learn. It must be patient-centered, safe,
14 effective, equitable, and efficient.

15 Summary of the Invention

16 The present invention is directed to an integrated, electronic patient record system
17 for providing real time point of care testing, data entry, billing, and safe treatment.

18 The present invention is further directed to a method for using the integrated,
19 electronic patient record system for providing real time point of care testing, data entry,
20 billing, and safe treatment.

21 Detailed Description of the Preferred Embodiments

22 The present invention according to the preferred embodiment includes a data
23 storage and processing device, or a server, connected via a wired and/or wireless local

1 area network, or LAN, and/or wide area network, or WAN, to at least one portable
2 computer and to clinical analytical equipment to provide real time point-of-care
3 laboratory results, vital signs, patient history, examination assessment, plan, and billing.
4 The server and clinical equipment can be connected via the wireless network or via a
5 universal equipment-integrating device connector, such as the CARELINK universal
6 connector by CARESIDE. The universal equipment-integrating device is capable of
7 physically connecting to and receiving input from devices, such as analytical devices for
8 the measurement of bodily functions and parameters. For example, the clinical
9 equipment or analytical devices may include a vital signs monitor, digital cardiogram
10 machine, a body composition analyzer to measure weight and percentage body fat, a
11 blood chemistry analyzer, urine dip stick analyzer, IV pump, hematology analyzer, digital
12 stethoscope, and any other laboratory or medical equipment that is capable of providing
13 output in a digital electronic format or where the output is scannable or otherwise
14 translatable or transferable into digital electronic format.. Each device would capture real
15 time data from the patient during the encounter and immediately transfer this data to the
16 electronic patient record. The device could be located in the physician's office or at a
17 distance, such as a nearby hospital.

18 Typically, these devices are equipped with in data input/output port, such as an
19 RS232 port. The universal equipment-integrating device connects these devices to a
20 mission critical file server that monitors data integrity and in turn communicates with the
21 patient's electronic record. Alternatively, these devices can be connected directly to the
22 server. For example, the server may be equipped with RS232 ports for direct connection

1 to the analytical devices or these devices may be equipment with USB ports for
2 connection with the USB ports of the server or client PC.

3 These clinical devices may provide such functions as testing, analysis, scanning,
4 diagnosis, assessment, communication with the patient, prognosis, and treatment plan.
5 Preferably, these results are automatically exported for incorporation into the patient
6 electronic chart. These clinical devices may also cross-link various codes, such as bar-
7 coded patient ID's, diagnosis codes, CPT codes and export these for incorporation into
8 the patient chart. Bar coding or similar representation of information can route the
9 patient ID key to their record, allowing for data capture relative to that patient. Bar
10 coding can also allow for inventory of sample medicines or medical office materials
11 inventory, thus facilitating ordering supplies, tracking medicines dispensed to a patient,
12 and billing patient for these medicines. Additionally, the bar code can facilitate patient
13 time and place tracking throughout the entire encounter. The mission critical file server
14 consists of a data processor(s), data storage device(s), and data transmission device(s).
15 The data transmission device(s) can include data lines, wireless transmission devices, and
16 the like. An example of a wireless transmission device is a wireless LAN using routers
17 operating at 2.4 Gigahertz using 802.11B protocol with the capacity to transmit at 11
18 Megabits/sec. The router can function as an access point within the local medical care
19 facility or link to an external medical care facility or provider. For example, the server
20 can transmit to a printer, electronic facsimile machine, portable computing device, and
21 the like. Alternatively, the network can also use a wireless system that operates at
22 another frequency, such as the RadioLan RF transmitter/receiver that operates at 5.8 GHz
23 frequency. This allows for faster and less congested transmission of data. The data

transmitted by these protocols is secure since it has 64 bit encryption capability. Only someone with a card that contains the encryption code can detect the signal. The fast access time allows for real time data capture during the patient encounter. The medical provider uses a touch screen capable notebook or subnotebook PC to allow for a faster, more intuitive system of data entry. By allowing for a range of 20 miles or more, medical facilities and providers can link together, thus sharing patient data and allowing for continuous access to the patient electronic record, or CAPER. This system would ultimately link doctors with the patient, nursing home, hospital, pharmacy and each other.

The LAN server runs software that allows it to communicate with and process information from a variety of devices, including the clinical devices, the portable computer, foreign servers, printers, communication devices, and the like.

The software also is capable of providing for data security, in that the software may encrypt selected data, may verify biometric data for user access to the network data, and may limit input and output of data. In a preferred embodiment, the system requires user login through a biometric device for access to the server and server functions. This would detect and deter intruders or unauthorized access.

Additionally, a preferred embodiment according to the present invention would assist with the framework for patient assessment, diagnosis, and treatment plan. By providing real time laboratory results, diagnosis can be made more quickly. Additionally, the software may be programmed to create templates using evidence-based medicine. These templates and reminder prompts facilitate optimal management of disease states such as cardiovascular disease, diabetes, cancer, and the like. To reduce medical prescription errors, a drop-down formulary acts as an aid to the clinician. The

1 drop-down formulary allows the clinician to scan through the available pharmaceuticals
2 and the like, select the item, further select the dose and other details of the prescription,
3 and transmit the selected order to the appropriate pharmacist, service provider, patient, or
4 the like. Thus, the system according to a preferred embodiment provides pass-through-
5 prescription of goods and services. For example, the system may transmit prescriptions
6 directly to a pharmacy and can also prescribe durable medical equipment and x-rays with
7 linked codes for medical necessity. Additionally, the clinician can generate a billing
8 charge from inside the note field. This process, know as pass-through-billing, is crucial
9 to the medical encounter. Medicare demands that the medical provider be in charge of
10 the billing process. In a preferred embodiment, the clinician selects a billing code for a
11 particular treatment. The billing code is inserted into the note field. The insertion of the
12 diagnosis code may be automatic upon request or completion of a service. For example,
13 when the clinician requests a particular laboratory analysis, the system automatically
14 inputs the billing code for the particular analysis into the note field. If the clinician
15 double-clicks the CPT code, a secondary screen arises that will ask for a diagnosis code
16 to link to the CPT code. If the two match the insurers criteria for that test, the process
17 transfers to the medical note. The clinician simply highlights and clicks the BILL button
18 or otherwise gives a BILL command to complete the process. The appropriate codes
19 allowable by the insurer can be programmed prior to the transactions and preferably
20 when the software is first setup. If the codes do not match, a prompt is given to the
21 medical provider identifying potential disagreement with the insurance carriers policies
22 on this order. Once in the chart, the two codes are linked and separated in brackets, such
23 as [].

1 The clinician then highlights the billing and diagnosis codes and instructs the
2 system to generate a transaction to the billing statement via a command, such as by
3 tapping the Bill action button on the screen. The system then generates a billing charge
4 that is ready for communication to the patient's insurance provider or to the patient.
5 After a code has been billed, the system inserts a symbol proximal to the code to indicate
6 that the code has been billed. For example, the system inserts a + in front of the code
7 such that a code of 902 becomes +902.

8 Other fields in the form are filled out by the data fields that are already linked to
9 the patient's chart since they were entered during the registration process. This process
10 of pass-through-billing can assist with all types of billable codes, including x-ray
11 procedures, evaluation and management, and durable medical equipment.

12 The server in a preferred embodiment according to the present invention may also
13 provide for processing and communication of insurance claims to a foreign server. The
14 insurance processing includes electronic billing, wherein the clinician selects and
15 transmits insurance claim codes, such as a HCFA 1500 form to the appropriate insuring
16 organization at the time of the medical exam. In the cases of patients with multiple
17 medical problems, the clinician can order the priority of each treatment such that the most
18 important treatment is claimed first. In this manner, the medical information does not
19 need to be processed by other personnel and therefore the time requirements per patient
20 are reduced and the possibility of error, including errors such as double billing, is greatly
21 reduced. Additionally, billing of the insurance claim occurs in real time, thus reducing
22 the time between delivery of service and reimbursement for service.

1 Other areas in the HCFA 1500 form are linked to and automatically filled in by data
2 fields from the patient's chart, which were filled in during the registration process.

3 The server is connected to a lightweight portable computer. This connection may
4 be via a hard line or via a wireless transmitter. In a preferred embodiment, the portable
5 computer is a notebook computer that transmits to a server via a wireless transmitter and
6 receiver. More particularly, the subnotebook computer is a B2130 , commercially
7 available from Fujitsu Corporation, and the wireless transmitter/receiver is a wireless RF
8 transmitter/receiver operating at 2.4 GHz commercially available from Lucent
9 Technologies Orinoco Line. An alternative device is the 5.8 GHz frequency RadioLan
10 140 PC card, commercially available from RadioLan Corporation. The long range
11 wireless links can be point-to-point or point-to-multipoint. This linking can be done
12 using Lucent Technologies CORs or RORs. These are connected to tower mounted
13 antennas that transmit the signal over great distances. The routers also act as local access
14 points providing local connections to the network. The routers and notebooks use access
15 cards to bridge the signal. With this long range access the clinician is always connected
16 to the patient's electronic record. If out of range, the data can be transmitted via
17 encrypted Internet e-mail or via a patient mini disc carrying the entire chart. The record
18 can also be printed into mini cards for patient portability of their record. The computer is
19 portable in order to allow the physician to continue to face the patient when inputting
20 data. Fixed computers may require the clinician to leave or turn away from the patient to
21 input data. These actions may be unsettling to the patient, in that the patient may feel a
22 lack of attention by the clinician. The portable computer also preferably includes a touch
23 screen, thereby enabling the clinician to move between charts, open templates, make

1 choices and the like by touching the screen. This function is important because it
2 approximates the actions of a clinician when inputting data onto a paper chart or
3 examining a patient. By approximating the paper chart method in this manner, a
4 preferred embodiment according to the present invention allows the clinician to remain in
5 a familiar state of mind, and not switch to another state of mind, one associated with
6 using a mouse or computer keys to give commands to the computer. Thus, this and other
7 features of the system make the performance and operation of the system intuitive to a
8 physician practicing with a paper system.

9 A key element of the present invention is speed of data transfer. These computers
10 and servers must operate at very fast speeds to allow for real time data entry and export.
11 Flow of information from the patient, clinical equipment, and other data generators to the
12 chart must be as close to real time as possible. This speed is only possible with very fast
13 and optimally configured computers, routers, and networks. The patient must not feel
14 that he or she is waiting for the computer to process a request of information. The
15 computer should be almost silent and invisible to the patient. Thus, the keyboard should
16 be quiet and the computer should not make any noise. The computer should also have
17 optimal battery life and software to prolong battery life. In a preferred embodiment, the
18 software generates visual screens that have a minimum of graphics. The graphical
19 component of the screens is reduced in order to minimize the amount of time required to
20 redraw a new screen when switching between screens. Quicker screen drawing allows
21 for more rapid switching between screens, and less idle wait time for the clinician and
22 patient.

1 The portable computer is capable of providing a template of a patient chart. The
2 template or templates are of pivotal importance during the patient encounter. It can be
3 provided by the software provider or can be created by the clinician. Thus, the system
4 according to a preferred embodiment offers flexibility to the clinician such that he/she
5 can select or create a template of his/her preference or customize an existing template.
6 For these purposes, the software, either the portable computer software or the server
7 software or both, includes an editor that can create and edit templates. The clinician must
8 order the elements in the template keeping in mind optimal arrangement for data
9 documentation both through the suggestion of the pertinent medical authority, such as
10 AMA, and insurance provider organization, such as the HCFA. The template should also
11 have the ability to increase equity for the clinician by assisting with optimal
12 documentation. The order of the elements should also allow for optimal placement of the
13 interface data from other office-based medical devices such as laboratory and vital signs
14 data.

15 The template may be highly structured, providing a highly detailed examination
16 protocol for the clinician to follow, such that the clinician is lead through the exam by the
17 template, or it may be very loosely structured, such that the physician can proceed
18 through the exam in the manner desired by the clinician. This second template, called a
19 non-formatted, open note template, may be desirable for physicians who are not used to
20 adhering to a protocol. Alternately, a physician can have multiple protocols from which
21 he selects one to use based on a parameter, for example, the patient's insurance provider.

22 The template includes a note field, wherein the clinician and other personnel can
23 enter observations. Data inputted into the note field is automatically presented in a time-

1 based order. For example, the most recently inputted data appears at the top or bottom of
2 the note field, according to the clinician's preference. The system is capable of providing
3 the automatic importing of results and data from other sources into the template. For
4 example, a consent form or data generated during a preliminary interview of the patient
5 by another health professional may be imported.

6 In the preferred embodiment of the present invention, the system imports this data
7 from other sources in a manner as to reduce the reading required by the clinician. For
8 example, interview questionnaires export only the choices selected by the patient as being
9 pertinent. These choices can be imported into the template in the appropriate field.
10 Evidence-based medicine should play an integral part in updating the template or
11 templates. These templates can also be shared with other physicians in the local and/or
12 wide area network. Additional pertinent data, such as suggested diagnostic tests and/or
13 test codes may also be imported and appended to the imported data. Thus, when a test is
14 ordered or a medication prescribed, the order or prescription is documented.

15 Preferably and where required, these templates also allow for the patient to be
16 followed via the wireless wide-area-network to other facilities where the templates allow
17 for optimal care. The hospital charting and billing is done in the same chart. A daily
18 progress note tracker will assist with compiling the patient's hospital stay and at the end
19 create the discharge summary with the click off the summary button. The same drug
20 formulary issued in the hospital so that when the patient returns to the office the same
21 chart is used. The billing codes are entered in real time, facilitating optimal care.
22 Additionally, the portable computer software offers a synoptic view of the template,
23 including a demographic window, a vital signs window, a laboratory analyses window, a

1 medications window, an allergies window, a family history window, a plan window, a
2 prior visit window, and the like. Thus, the clinician has a simultaneous view of all the
3 pertinent information for a single patient, and is not required to switch between windows
4 to double-check patient facts. This is the same principle around which the cockpits of
5 fighter jets are designed. . These windows may a have a drop down menu that allows the
6 clinician to select a choice for one of the fields in the window. At a glance the doctor can
7 see all the meds, all diagnosis, medical notes, jump to the insurance or demographics
8 region.

9 These components and features combined form a wireless, paperless medical care
10 system that is easy to use, always available, reduces data entry time and errors, and can
11 provide real time point-of-care testing, data entry, treatment of patients and billing.

12 A method for using the system set forth in the foregoing is also included within
13 the present invention. In a preferred embodiment, utilization of the system would involve
14 a patient entering personal information directly through a workstation or by recitation to
15 data entry personnel. The patient could also e-mail their medical information prior to the
16 encounter. Such information can include age, allergies, symptoms, family history, and the
17 like. This is the primary triage area. The patient's digital picture and signature are also
18 obtained at this point and entered into the patient's electronic medical records. Next,
19 appropriate analytical devices determine the patient's vital signs such as blood pressure,
20 heart rate, height, weight, and the like. Any blood testing that has been ordered prior to
21 the visit can also be done and linked electronically to the patient's chart. This is the
22 secondary triage area. The use of equipment made for point of care testing like the
23 CARESIDE analyzer play an integral part in this step. Next, the clinician evaluates and

1 examines the patient. As the patient speaks, data is captured by the clinician with the
2 keyboard and entered into the patient's electronic medical records. The templates are
3 used for optimal examination and documentation.

4 Certain modifications and improvements will occur to those skilled in the art upon
5 a reading of the foregoing description. By way of example, the system according to the
6 present invention is not limited to use in clinics and hospitals, but can be used in nursing
7 homes, dentist's offices ambulances, ships, airplanes, etc. Also, non-medical and
8 administrative information pertaining to the patient can also be electronically stored and
9 transferred within this system, including but not limited to, patient insurance cards,
10 patient consent, and the like. All modifications and improvements have been deleted
11 herein for the sake of conciseness and readability but are properly within the scope of the
12 following claims.

13